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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/150,813	09/11/98	GRAINGER D	295.027US1

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SCHWEGMAN LUNDBERG WOESSNER & KLUTH
P O BOX 2938
MINNEAPOLIS MN 55402

EXAMINER	
MURPHY, J	

ART UNIT	PAPER NUMBER
1644	11

DATE MAILED: 02/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/150,813	GRAINGER ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *21 December 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *1-16,18,19,21,23-33,35-40 and 45-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,20,22,34,41-44 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☒ Other: *Sequence Comparison A* .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of species (i), claims 17, 20, 22, 34 and 51 in Paper No. 10, 12/21/99 is acknowledged. Claims 41-44 have been rejoined for examination. The traversal is on the ground(s) that the pathological conditions recited are associated with a chemokine-induced activity and therefore are not independent. However, the test for propriety of restriction is not whether the inventions are related, but rather whether they are distinct and whether it would impose a burden on the examiner to search and examine multiple inventions in a single invention. A search of the literature on methods of treatment of, for example, low bone mineral density, would not be expected to reveal art for a method of treatment for autoimmune disorders. The necessity of separate searches would be unduly burdensome. Additionally, the species as delineated in the restriction requirement (Paper No. 8, 10/18/99) are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the restriction requirement).

Therefore, the requirement is still deemed proper and is therefore made FINAL. Claims 1-16, 18-19, 21, 23-33, 35-40 and 45-50 are withdrawn from further consideration by the examiner, 37 CFR 1.48(b)

Claims 17, 20, 22, 34, 41-44 and 51 are under consideration.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 51 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki , 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-17, 20, 22, 34, 41-44 and 51 are rejected under 35 U.S.C 112, first paragraph, because the specification, while being enabling for a method of preventing or inhibiting an indication associated with a chemokine-induced activity which comprises administration of a Chemokine peptide 3 polypeptide selected from the group consisting of sequences set forth in SEQ ID Nos: 1, 7, 38, 40-44, 65-68 and 72-74, does not reasonably provide enablement for any other method of preventing or inhibiting an indication associated with a chemokine-induced activity which comprises administration of a Chemokine peptide 3 polypeptide, or variants or derivatives thereof. There is not adequate guidance as to the nature of the variants or derivatives which Applicants claim, i.e. differing polypeptide sequences which exhibit a similar activity to a specific polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with this claim.

Claims 1-17, 20, 22, 34, 41-44 and 51 are overly broad in the recitation of "Chemokine peptide 3", since no guidance as to what constitutes " Chemokine peptide 3" polypeptide is provided within the claims. The broad scope of claims 1-17, 20, 22, 34, 41-44 and 51 can be read to encompass any isolated polypeptide. There is no guidance provided in the specification as to how one of ordinary skill in the art would generate a polypeptide other than those exemplified in the specification. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 1-17, 20, 22, 34, 41-44 and 51 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 17, 20, 22, 34, 41-44 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 17, 20, 22, 34, 41-44 and 51 are indefinite in that they only describe the peptide of interest by an arbitrary protein name. There is nothing in the claims which distinctly claims the protein and variants thereof. For example, others in the field may isolate the same

protein and give said protein an entirely different name. Applicant should particularly point out and distinctly claim the peptide 3 molecule and variants thereof by claiming structural characteristics associated with the protein (e.g. amino acid sequence, molecular weight, etc.). Claiming biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what that protein is.

5b. Claims 17 and 20 are vague and indefinite in the recitation of the term "indication". The term "indication" is not defined within the claim, and it is unclear what will be indicative of a chemokine-induced activity. The metes and bounds of claims 17 and 20 cannot be determined due to the indefinite nature of the term "indication". Claims 41-44 are rejected insofar as they depend on the recitation of the term "indication" in claim 17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 17, 20, 22, 34 and 51 are rejected under 35 U.S.C. 102(a) as being anticipated by Gong et al. (1997).

Gong et al. (1997) teaches a method of inhibition of arthritis, arthritis being an indication of a chemokine-induced activity, in MRL-lpr mouse through the administration of amino-terminal deleted MCP-1 polypeptide (Figure 1, page 132). The polypeptides taught by Gong et al. (1997) comprise the sequences defined as peptide 3 polypeptides as disclosed in the instant application (page 131, column 2, second paragraph; For an example, see Sequence Comparison A). Therefore, the disclosure of Gong et al. (1997) anticipates the indicated claims by teaching a method of administration of polypeptides comprising the sequences disclosed as peptide 3 in a mammal to prevent (page 132, Figure 1) and inhibit (page 135, Figure 5) a chemokine-induced activity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 17, 20, 22, 34 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gong et al. (1995).

Gong et al. (1995) teaches a method of inhibiting MCP-1 induced chemotaxis, an indication of chemokine-induced activity, with amino-terminal truncated MCP-1 polypeptides (Figure 5, page 635). Additionally, the amino-terminal truncated MCP-1 polypeptides taught in Gong et al. inhibited MCP-1 induced Ca^{++} mobilization (Figure 6, page 636), another indication of chemokine-induced activity. The polypeptides taught by Gong et al. (1995) comprise the sequences defined as peptide 3 polypeptides as disclosed in the instant application (Figure 2, page 633; For an example, see Sequence Comparison A).

Gong et al. (1995) differs from the disclosed invention by using a cell based assay system, while the instant claims are drawn to administration of an inhibitor of a chemokine-induced activity to a mammal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer to a mammal, peptides that correspond to regions of the amino-terminal truncated peptides of Gong et al. (1995) to inhibit a chemokine induced activity. The motivation is provided in Gong et al (1995) (page 638, column 2, second paragraph), which teaches that one of the amino-terminal truncated MCP-1 polypeptides will be in the therapeutic range of effectiveness and will be useful for development of further MCP-receptor antagonists with high potency, including a more detailed analysis of the amino-terminal region and determination of the roles of other regions of MCP-1 in vivo. Gong et al. (1995) teaches the expectation of

success, in that in a rat alveolitis system, MCP-1 antibodies have been reported to inhibit in vivo function.

8. Claims 17 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gong et al. (1995), in view of Sozzani et al. (1996).

The teaching of Gong et al. has been set forth above. Gong et al. (1995) differs from the disclosed invention by using a cell based assay system, while the instant claims are drawn to administration of an inhibitor of a chemokine-induced activity to a mammal.

Sozzani et al. teaches that MCP-1 induces arachidonic acid (Figure 8, page 4669). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the amino-terminal truncated MCP-1 polypeptides of Gong et al. (1995) as inhibitors of arachidonic acid production. Since arachidonic acid is the immediate precursor of the leukotrienes, thromboxanes and prostaglandins, inhibition of arachidonic acid synthesis will inhibit the synthesis of leukotrienes, thromboxanes and prostaglandins. The motivation for inhibiting arachidonic acid production is provided in Sozzani et al. (page 4670, column 2, first paragraph) who teach that the metabolism of arachidonic acid is implicated in monocyte chemotaxis.

Conclusion

9. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1644
February 17, 2000

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER